DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

M3908V1

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-62

June 27, 2000

Julio F. Villegas, President
United States Blood Bank
351 NW 42nd Avenue, Suite 103
Miami, Florida 33126

Dear Dr. Villegas:

During an inspection of your licensed blood bank from May 10 through 22, 2000, our investigators, Clara E. Santiago and Raymond A. Lyn, documented serious violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), and the regulations for blood and blood components [Title 21, Code of Federal Regulations, Parts 600-680 (21 CFR 606-680)].

The inspection revealed you have failed to maintain complete and accurate records from which unsuitable donors may be identified so that products from such individuals will not be distributed. Numerous donors who were reactive for at least one or more viral markers were not placed in your donor deferral registry from June 9, 1999 to May 11, 2000. Your attempt to update your donor deferral registry during the inspection was insufficient and incomplete in that nineteen donors listed in the permanent deferral logs and thirty donors listed in the temporary deferral logs maintained on your mobile units were not included in your update. In addition, your permanent and temporary deferral logs maintained on your mobile units failed to include the same information.

The inspection also revealed you have failed to adequately determine the suitability of persons to serve as whole blood donors. Our investigators documented six donors with previously reactive viral marker test results who were accepted for donation, two donors who should have been deferred based upon their answers to medical history questions and one donor who was accepted for donation within twenty-four days of a previous donation. Some donor record files failed to include donor signatures, product information, and inaccurately recorded male/female only questions.

Our investigators also documented that you have failed to establish, maintain and/or follow adequate written standard operating procedures (SOP's). For example, SOP's are not established for error/accident reporting, handling of complaints, distribution of blood products and investigation/disposition of returned blood products. Your SOP's for donor suitability, hematastat/copper sulfate quality control, dietary and bed scales quality control and transfusion safety/lookback are inadequate and are not being followed.

We note that several of these deficiencies were cited during our previous inspection of your blood bank in August of 1999 and that your written response to the List of Observations (FDA Form 483) dated September 9, 1999 stated that these deviations had been corrected.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood and blood components produced and issued by your blood bank are in compliance with the Act and the federal regulations. You should take prompt action to correct these violations. Your failure to correct these violations may result in further administrative and/or regulatory action being taken by FDA without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including examples of any documentation showing that corrections have been achieved. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District